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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,394	10/23/2003	Marlin L. Alford	13241US02	8465

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MCANDREWS HELD & MALLOY, LTD.
500 WEST MADISON STREET
SUITE 3400
CHICAGO, IL 60661

EXAMINER

REDDING, DAVID A

ART UNIT PAPER NUMBER

1744

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,394

Applicant(s)

ALFORD ET AL.

Examiner

David A. Redding

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/22/04</u> . | 6) <input type="checkbox"/> Other: ____. |



DETAILED ACTION***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "13" has been used to designate both top of organ chamber and screws; reference number 11 the bubble trap in figure 1 and another part in figure 2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because fails to show element number 22,31,32,33 as described in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must

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be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,677,150. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn more broadly they would be anticipated by the patented claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,6,9-16,18,20,25,29,33, are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,586,438 (Fahy).

Fahy discloses an organ perfusion and transportation system which comprises an organ container (11), a bubble remover (111) which is comprised of two compartments separate from the organ container (11) and an oxygenator placed in between lines (119,120) to provide oxygen and remove carbon dioxide from the perfusate (col.16, lines 61-col.17, line 5). The bubble trap (111) had a head space and a venting valve (116). The system also discloses that the organ is connected to the perfusion tube via a cannula which have tubular stems and which is considered to read on the claimed "adapter".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,586,438 (Fahy) as applied to claim 1 above and further in view of USP 5,326,706 (Yland).

The Fahy patent discloses the use of a roller pump to provide peristaltic flow of the perfusate (col.14, lines 50-54). The reference is silent as to the use of impeller pumps. The Yland et al. patent discloses an organ perfusion system which provides peristaltic flow using an impeller pump (col.15, lines 60-67).

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Accordingly, it would have been obvious to one skilled in the art to use an impeller pump in the Fahy system in view of the known use in Yland et al.

Further, it would have been obvious to one skilled in the art to modify the bubble remover in Fahy by increasing the cross-section of the upper region in order to increase the contact surface area and correspondingly increase the rate of removal of the trapped gas.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,586,438 (Fahy) as applied to claim 1 above, and further in view of USP 6,046,046 (Hassanein).

Fahy is silent as to the use of membrane filter. The Hassanein patent discloses an organ perfusion and transportation system which includes a hollow-fiber membrane oxygenator (38) that is self-contained. Accordingly it would have been obvious to one skilled in the art to use the membrane oxygenator of Hassanein in the Fahy system in view of the oxygenates known use in organ perfusion systems.

Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,586,438 (Fahy) as applied to claim 6 above, and further in view of USP 5,856,081 ('081).

The '081 patent discloses an organ perfusion system which uses "quick-disconnect" connectors between the various flow lines and system elements (oxygenates, organ container, etc) (see description of figure 1).

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Accordingly it would have been obvious to one skilled in the art to use the “quick-disconnect” connectors for connecting the various flow lines to chambers in Fahy in view of the advantages and benefits of quick assembly/disassembly in the ‘081 system.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy, ‘081 patent as applied to claim 7 above, and further in view of US publication 2003/0163078 (Fallen et al.).

Falen et al. discloses an organ perfusion system to support a patient during surgery in which the various flow tubing of the system is color coded with the various inputs/outputs that the tubing is connected to. Accordingly it would have been obvious to one skilled in the art to color code the various tubing and corresponding connections in the Fahy system to provide ease of assembly in view of the known practice as disclosed in Fallen et al.

Claims 16-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,046,046 (Hassanein) in view of USP 5,856,081 (‘081).

Hassanien discloses an organ perfusion system comprising an organ container (20) and oxygenator (38) and a bubble remover (216). The organ container includes a cover (22) having the adapters (120,122,124) connected thereto. The adapters are considered to read on the limitations defined in claims 21-25. A close review of figure 2 shows that the distal ends of the adapters have a larger circumference than the portion of the adapters which meets the ends of the arterial and venous portions of the organ. The reference is silent as to whether the adapters are connected to the tubing by a “quick-disconnect” connector.

The '081 patent discloses an organ perfusion system which employs "quick-disconnect" connectors throughout. Accordingly, it would have been obvious to one skilled in the art to provide the adapters in Hassanein with quick-disconnect connector in view of the known practice in the '081 patent.

Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,586,438 (Fahy) as applied to claim 1 above, and further in view of the JP patent JP8169801 abstract.

The Fahy patent does not disclose the type of oxygenator that could be used with the device. The JP patent abstract discloses a hollow fiber oxygenator which reads on claims 30-32 for use for organ perfusion devices. Accordingly it would have been obvious to one skilled in the art to use the hollow-fiber oxygenator of the JP patent abstract in the Fahy device in view of the oxygenators known use with organ perfusion systems.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USP 3,893,926 (Awad) discloses an oxygenator which uses silastic tubing. USP 6,673,594 discloses a device generally related to the claimed invention. US patents to Westcott and Donlon discloses connectors for organs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-9178. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David A Redding
Primary Examiner
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DAR